Status: Open 8 a.m.–8:15 a.m., June 17, 1999; Closed 8:15 a.m.–5:30 p.m., June 17, 1999; Closed 8 a.m.–5:30 p.m., June 18, 1999.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals which will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects which will lead to improvements in the delivery of occupational safety and health services and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters to be Discussed: The meeting will convene in open session from 8:00–8:15 a.m. on June 17, 1999, to address matters related to the conduct of Study Section business. The remainder of the meeting will proceed in closed session. The purpose of the closed sessions is for the Safety and Occupational Health Study Section to consider safety and occupational health related grant applications. These portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6) title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Pervis C. Major, Ph.D., Scientific Review Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505. telephone 304/285–5979.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 30, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–11634 Filed 5–7–99; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0791]

Agency Emergency Processing Under OMB Review; Survey of Medical Device Manufacturers for Year 2000 Compliance of Manufacturing Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns a survey of medical device manufacturers for Year 2000 compliance of their manufacturing systems. The list of the Year 2000 compliant facilities will be made available to the public via the World Wide Web.

DATES: Submit written comments on the collection of information by May 17, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. FDA is requesting certain information on the Year 2000 compliance status of medical device manufacturing processes. This information is needed immediately in order to allow the agency to: (1) Assess the impact of the Year 2000 problem on the continued availability of an adequate supply of safe and effective medical devices and medical/surgical supplies; (2) properly advise the health-care industry and the U.S. public regarding the preparedness of the medical device industry; and (3) assess the need for additional government actions to address potential supply disruptions. This information is essential to the mission of the agency. The potential existence of Year 2000 problems in the medical device industry could pose potentially serious health and safety consequences. The use of normal clearance procedures would prolong the time needed to assess Year 2000 compliance by regulated industry.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Survey of Medical Device Manufacturers for Year 2000 Compliance of Manufacturing Systems

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) permits the Secretary of Health and Human Services (the Secretary) to disseminate information regarding food, drugs, devices, and cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Manufacturers will be asked to provide a status on their Year 2000 readiness and will also be asked if they have contingency plans. The survey will also ask if they have tested, verified, and certified their systems. Finally, the request will ask for a single point of contact at the manufacturer to discuss information.

The manufacturer will be able to provide facsimile, electronic, or paper copy of the information to FDA for inclusion in the web site data base. Government agencies, as well as health-care facilities and the general public, will have access to the web site to be able to assess their vulnerability to Year 2000 problems and to take corrective actions, if necessary, in advance of January 1, 2000. The posting of information on compliant facilities is designed to provide health care facilities with a positive statement as to the status of compliant firms.

Respondents: Medical Device Manufacturers

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
13,500	1	13,500	13	175,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's mailing lists were used to estimate the number of medical device manufacturers who would be subject to this collection. FDA estimates that it will take manufacturers an average of 13 hours to collect, prepare, and submit the requested information. These estimates include allowance for variance in the number of devices to be reported by a manufacturer.

Dated: May 5, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–11734 Filed 5–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1069]

Changes in the Procedures for Providing Public Notice of the Availability of Completed Environmental Assessments and Findings of No Significant Impact

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing changes in the procedures used for providing public notice of the availability of completed environmental assessments (EA's) and findings of no significant impact (FONSI's) for new drug applications (NDA's), abbreviated new drug applications (ANDA's), and supplemental applications.

EFFECTIVE DATE: May 10, 1999.

ADDRESSES: Copies of EA's and FONSI's are available on the Internet at ''http://www.fda.gov.cder/foi/index.htm'' or may be requested by writing the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5633.

SUPPLEMENTARY INFORMATION: Under the National Environmental Policy Act of 1969 (NEPA), Congress declared that it will be the continuing policy of the Federal Government to ''use all practicable means and measures, including financial and technical assistance, in a manner calculated to foster and promote the general welfare, to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations of Americans.'' (See 42 U.S.C. 4331(a).) NEPA requires all Federal agencies to include in every recommendation or report for major Federal actions significantly affecting the quality of the human environment a detailed statement assessing the environmental impact of, and alternatives to, the proposed action and to make available to the public such statements. (See 42 U.S.C. 4332 and 40 CFR 1506.6.)

FDA regulations in part 25 (21 CFR part 25) govern compliance with NEPA, as implemented by the regulations of the Council on Environmental Quality (CEQ) in 40 CFR part 1500. Under FDA regulations, actions to approve NDA's, ANDA's, and supplements to existing approvals ordinarily require the preparation of an EA. (See § 25.20(l).)

In accordance with FDA regulations, FDA must make completed EA's and FONSI's for NDA's, ANDA's, and supplements available to the public upon request in accordance with the procedures in 40 CFR 1506.6. (See § 25.51(b)(2).) The regulations at 40 CFR 1506.6 require that certain environmental documents be made available to the public under the provisions of the Freedom of Information Act (5 U.S.C. 552) and that these documents be made available to the public without charge, to the extent practicable. (See 40 CFR 1506.6(f).) This is the procedure used by CDER to provide completed EA's and FONSI's for NDA's, ANDA's, and supplements for human drugs to the public when they are requested.

Although not required by regulation, CDER has also periodically published notices in the **Federal Register** (57 FR 18887, 61 FR 49470, 62 FR 22960, 63 FR 27300) that provide a listing of EA's and FONSI's that are available for NDA's, ANDA's, and supplements. FDA is announcing that CDER will no longer publish such notices, because the environmental documents are now available on the Internet.

In 1996, FDA established the Center for Drug Evaluation and Research (CDER) Freedom of Information Office Electronic Reading Room, which can be accessed through the Internet at ''http://www.fda.gov.cder/foi/index.htm''. The electronic reading room provides a listing of applications approved by CDER and electronic copies of agency documents used to support the approval of the applications under the heading ''Drug Approval Packages.'' The agency documents include an EA and FONSI for each application unless the action was categorically excluded from the requirement to prepare an EA. (See § 25.31.)

Publication of a notice in the **Federal Register** announcing the availability of completed EA's and FONSI's for NDA's, ANDA's, and supplements duplicates the information available through the CDER Freedom of Information Office Electronic Reading Room. Therefore, to promote efficient operations, FDA will discontinue publication of such **Federal Register** notices, effective immediately.

Dated: April 30, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–11583 Filed 5–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0611]

Determination of Regulatory Review Period for Purposes of Patent Extension; Femara®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Femara® and is publishing this notice